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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/510,869

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EXAMINER

EREZO, DARWIN P

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,869	Applicant(s) HEINRICH ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-44 is/are pending in the application.
- 4a) Of the above claim(s) 26-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-25 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is in response to applicant's amendment filed on 10/28/08.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 6, 8, 9, 12, 15-17, 20, 21 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,176,864 to Chapman.

Independent Claim 1: Chapman disclose a device for joining a first body vessel to a second body vessel (anastomosis device), comprising: a concentric inner member **20** having a distal end portion and defining a longitudinal axis; a concentric outer member **40** defining a lumen dimensioned to receive the inner member therein; and a radially expandable anchor **30** disposed at the distal end of the inner member, the expandable anchor having an initial condition wherein the expandable anchor is disposed between the outer member and the inner member (Fig. 4) and an expanded condition; and a sheath (everted portion of graft member **10**) located at the distal end of the expandable member for defining a shape of the expandable anchor in the expanded condition such that a distal end of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition (see Fig. 9).

Independent Claim 15: Chapman discloses a device for joining a first body vessel to a second body vessel (anastomosis device), comprising: a pair of concentric

tubular sleeves including an outer sleeve **40** and an inner sleeve **20**, each of the pair of concentric tubular sleeves having a distal end portion and a proximal end portion; and a radially expandable anchor **30** operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion and a distal end portion capable of providing a radially outward force when the anchor expands. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the examiner's position that radially expandable anchor of Chapman expands along its length, thus the proximal and distal portion of said expandable anchor will provide a radially outward force. It is further noted that the first body vessel or the second body vessel are not positively recited in the claims.

Claims 2 and 16: The expandable anchor is made from a foam-like material (col. 5, ll. 36-45)

Claims 4, 17 and 20: The distal end portion of the expandable anchor is shown to be radially larger than a proximal end portion of the expandable anchor when in the expanded condition (Fig. 9) to prevent removal of the anastomosis device, and wherein the expandable anchor has a thin-walled cylindrical shape when in the initial condition.

Claims 6 and 8: The inner member is an inner tubular sleeve defining a central lumen extending therethrough, which permits liquid to pass therethrough and drain through the inner tubular sleeve.

Claims 9 and 21: The expandable anchor is a hollow tube that defines at least one longitudinally oriented passage extending completely therethrough when in the expanded condition.

Claim 12: The outer surface of the everted portion of graft member **10** act as a grasper to the interior surface of the vessel **12**.

Claim 44: The radially expandable anchor is fully capable of providing a radially outward force along the length of the anchor when said anchor expands.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 3 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman, as applied to the rejections above, and in view of US 2,898,913 to Ritter et al.

Chapman discloses all the limitations of the claims except for the expandable anchor having a frustoconical shape when in the expanded condition. However, Ritter discloses that using connectors with frustoconical shapes are well known in the art, as seen in Fig. 3. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Chapman to have a frustoconical shape since it is well known in the art, as shown by Ritter, and since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

8. Claims 5, 13, 14, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman, as applied to the rejections above, and in view of US 5411,520 to Nash et al.

Chapman discloses all the limitations of the claims except for the expandable anchor radially expands upon contact with moisture. Instead, Chapman discloses a self-expanding foam-like expandable anchor. However, the use of foam expanded by fluid is well known in the art. For example, Nash discloses an expanding foam plug

that expands in the presence of blood. Thus, the self expanding foam of Chapman and the foam expandable in the presence of blood are well known foam expandable equivalents. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the foam of Chapman for the foam of Nash because it has been held that a substituting one known element for another equivalent element will yield predictable results. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

It is also noted that the foam taught by Chapman is collagen, which is a known bioabsorbable material that is absorbed over time.

9. Claims 7 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman, as applied to the rejections above, and in view of US 6,241,743 to Levin et al.

Chapman discloses all the limitations of the claimed invention except for the inner tubular sleeve includes a region near its distal end which is porous. However, Levin discloses another anastomosis device having a structure 12 defining pores in order to provide the graft flow based nutrition (col. 5, ll. 62-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide pores in the distal end of the inner tubular sleeve of Chapman since it would provide flow based nutrition to the everted graft at the distal end.

10. Claim 10 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chapman.

With regards to the limitation that the device further comprises a control unit, remotely located, for operating the anastomotic device, it would have been inherent for the device of Chapman to have a control unit in order to manipulate the device. If this is not found persuasive, then it would have been obvious to one of ordinary skill in the medical art to provide a control unit to the device of Chapman in order to remote control the deployment of the expandable anchor.

Response to Arguments

11. Applicant's arguments with respect to the Chapman reference have been considered but are moot in view of the new ground(s) of rejection. Note that the rejections under the Chapman reference has been modified in view of the new limitations to the claims, thus, the modified rejection is a new grounds of rejections. Please see the rejections above as to how the examiner is now interpreting the Chapman reference.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773